

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/041,975 03/13/98 ALIZON

M 2356.0011-06

HM12/0517

EXAMINER

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PARKIN, J

ART UNIT

PAPER NUMBER

1648

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DATE MAILED:

05/17/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/041,975

Applicant(s)

Alizon et al.

Examiner

Jeffrey S. Parkin, Ph.D.

Group Art Unit

1648

Responsive to communication(s) filed on 2/29/99

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 23-38 is/are pending in the application.

Of the above, claim(s) 26-38 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 23-25 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) 07/038,330.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**Detailed Office Action**

***Status of the Claims***

1. Acknowledgement is hereby made of the Amendment and Response filed 26 October, 1998, and 19 February, 1999, respectively. The amendment resulted in the cancellation of claims 1-6 and 22 without prejudice or disclaimer and the introduction of new claims 23-38.

5 A restriction requirement was sent out in response to the submission of these claims. Applicants' election with traverse of Group I (claims 23-25) in the Response (Paper No. 8) is acknowledged. The traversal is based upon the premise that it would not pose a serious burden upon the Examiner to search the claimed subject matter together. This is not found persuasive for the reasons of record noted in the original restriction requirement (Paper No. 7). As previously noted, each of the designated groups is directed toward a genotypically/phenotypically independent and distinct isolate. Each of the claimed viruses will contain different nucleotide and/or amino acid sequences and attendant virological, immunological, and pathological properties. Accordingly, a separate search will be required for each designated group.

10 **The requirement is still deemed to be proper and is therefore made FINAL.** Claims 26-38 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Applicants are reminded that a complete response to the final rejection must include cancellation of the non-elected claims or other appropriate action (refer to 37 C.F.R. § 1.144 and M.P.E.P. § 821.01).

15  
20  
25 **35 U.S.C. § 112, Second Paragraph**

2. The previous rejection of claims 1-3 and 5-7 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to

particularly point out and distinctly claim the subject matter which applicant regards as the invention, is moot in view of the cancellation of these claims.

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**35 U.S.C. § 102**

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15 4. The previous rejection of claim 4 under 35 U.S.C. § 102(b) as being anticipated by Alizon et al. (1984), is moot in view of the cancellation of this claim.

20 5. The previous rejection of claim 4 under 35 U.S.C. § 102(b) as being anticipated by Wain-Hobson et al. (1985), is moot in view of the cancellation of this claim.

**35 U.S.C. § 103(a)**

25 6. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

30 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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5           Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10           7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the 15 time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

20           8. The previous rejection of claims 5 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Alizon et al. (1984) and Wain-Hobson et al. (1985) in view of Stabinsky (1988) and Saiki et al. (1987), is moot in view of the cancellation of these claims.

#### New Grounds of Rejection

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##### **35 U.S.C. § 112, Second Paragraph**

30           9. Claims 23-25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The reference to genetic differences in claim 23 is ambiguous since the precise genotypic properties of the virus are not clear. For instance, does the claim language refer to an HIV-1 variant that differs at the nucleotide sequence level or at the amino acid level? Does the claim language encompass changes

within an entire full-length gene (i.e., *gag*), or only a portion of it (i.e., the NC, CA, or MA coding portions)? Appropriate clarification and amendment of the claim language as supported by the disclosure are required (i.e., A purified HIV-1 variant virus comprising the following characteristics: (I) the virus differs by more than 3.4% at the nucleotide sequence level in the *gag* gene as compared to the HIV-1 isolates IIIB, BRU, and ARV-2; (ii) the virus differs by more than 3.1% in the *pol* gene as compared to the HIV-1 isolates IIIB, BRU, and ARV-2 . . . ).

The reference to an HIV-1 variant containing the same genetic structure as compared to HIV-1 is confusing. It is not readily manifest to the skilled artisan how a virus, which is a genetic variant (i.e., contains a different genotype, and presumably phenotype, from the prototypical HIV-1 isolate) could maintain the same "genetic structure." If the viruses contained the same genotypes, they would not be variants. Alternatively, if applicants are simply referring to the overall genetic organization of the virus (i.e., an HIV-1 variant that displays the common genomic organization of HIV-1 viruses [e.g., 5'-LTR-*gag-pol-vpr-vif-tat-rev-vpu-env-nef-LTR-3'']), than this should clearly be noted in the claim language. Appropriate clarification and amendment of the claim language as supported by the disclosure are required.*

**35 U.S.C. § 112, First Paragraph**

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it 30 is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 23-25 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claimed invention appears to be broadly directed toward any purified HIV-1 variant that differs genetically in the *gag*, *pol*, and *env* coding regions from three known HIV-1 prototypes (e.g., IIIB, BRU, and ARV-2). As such, the claim language encompasses a large genus of viruses. However, the disclosure only describes the isolation of a single novel HIV-1 isolate, designated LAV-1<sub>MAL</sub>. A molecular clone was identified and its nucleotide sequence ascertained. This is the only virus described in the disclosure. The disclosure fails to provide any evidence suggesting that additional HIV-1 isolates, meeting the claimed limitations, were isolated and purified. Although vague reference was made to "variants of the new virus" on page three of the specification (first paragraph), the disclosure fails to provide any guidance pertaining to the genotypic and phenotypic properties of any of these purified variants. Moreover, the disclosure is clearly directed toward a novel HIV-1 isolate, designated LAV<sub>MAL</sub>, as set forth throughout the disclosure (e.g., SUMMARY OF THE INVENTION, pages 2-6; EXPERIMENTAL PROCEDURES, pages 18 and 19; bridging paragraph, pages 22 and 23; etc.). Legal precedence also dictates that the disclosure of a single species, in combination with generic methods for its isolation, does not provide sufficient written description for the broad genus *per se*. *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398 (C.A.F.C. 1997). *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 U.S.P.Q.2d 1601,

1606 (Fed. Cir. 1993). *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 U.S.P.Q.2d 1016-1031 (C.A.F.C. 1991). Thus, the skilled artisan would reasonably conclude that while applicants were in possession of a purified HIV-1 isolate designated MAL, they were  
5 not in possession of any other HIV-1 variants.

**35 U.S.C. § 102**

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this  
10 section made in this Office action:

A person shall be entitled to a patent unless --

15 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**35 U.S.C. § 103(a)**

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this  
20 Office action:

25 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

35 40 14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims

was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the 5 time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

15. Claims 23-25 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Myers et al. (1990). As discussed *supra* in paragraph 10 9 of this Office action, the precise genotypic/phenotypic characteristics of the claimed invention have not been clearly set forth. Moreover, since this application fails to provide an 15 adequate written description of the claimed invention as discussed *supra* in paragraph 11, priority cannot be extended under 35 U.S.C. §§ 119 or 120. Accordingly, the following art rejection has been applied. Myers et al. (1990) provide the complete nucleotide sequence of a novel purified HIV-1 isolate designated Z2Z6. This 20 isolate is genetically related to the HIV-1 isolates ELI and MAL and appears to be only distantly related to the isolates BRU, IIIB (or HXB2), and ARV-2 (SF-2). Nucleotide sequence and amino acid analysis demonstrated that this isolate appears to vary from the aforementioned prototypical isolates BRU, IIIB, and ARV-2 by at 25 least 3.4%, 3.1%, and 13.0% in the *gag*, *pol*, and *env* coding regions, respectively. Thus, this isolate appears to meet all the limitations of the claimed invention. Moreover, because of the close genetic relatedness between Z2Z6 and the isolates ELI and MAL, one of ordinary skill in the art would reasonably expect 30 nucleic acid probes and antibodies specific for MAL to also recognize Z2Z6 nucleic acids and antigens.

***Finality of Office Action***

16. Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

5           **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

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***Correspondence***

20           17. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

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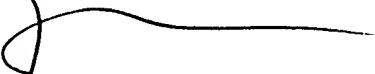
30           18. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Chris Eisenschenk, J.D., Ph.D., can be reached at (703) 308-0452. Any inquiry of a general nature or relating to the status of this application should be

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Serial No.: 09/041,975  
Applicant(s): Alizon et al.

directed to the Group 1600 receptionist whose telephone number is  
(703) 308-0196.

Respectfully,

  
Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

07 May, 1999

  
LAURIE SCHEINER  
PRIMARY EXAMINER